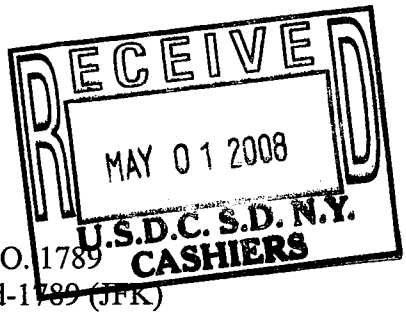
IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

'08 CIV 4163



IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MDL NO. 1789 1:06-md-1789 (JFK)
BIRDELLA BLAKELY, Plaintiff, v. MERCK & CO., INC., Defendant.	Civil Action No.: **COMPLAINT AND** **DEMAND FOR JURY TRIAL**

Plaintiff BIRDELLA BLAKELY (alternatively referred to as "Plaintiff"), residing at RRTE 1, Box 181, Boley, Oklahoma 74829, by and through her undersigned attorneys, hereby sues the defendant, MERCK & CO., INC., (hereinafter referred to as "Merck" or "Defendant"), which has its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889-0100, and alleges as follows:

GENERAL BACKGROUND AND OVERVIEW OF CLAIMS

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the

pharmaceutical product known as Fosamax (hereinafter referred to as "Fosamax" or "the subject product").

2. At all times material hereto, Defendant designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold Fosamax for the prevention and treatment of osteoporosis as well as the treatment of Paget's disease.

3. As a result of the defective nature of Fosamax, those persons who were prescribed and ingested Fosamax, including Plaintiff, have suffered and continue to suffer severe and permanent injuries, including osteonecrosis of the jaw.

4. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

5. Defendant knew of the significant risk of dental and oral complications caused by ingestion of Fosamax, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.

6. Defendant failed to conduct adequate post-marketing surveillance of Fosamax after it began marketing, advertising, distributing and selling the product.

7. Consumers, including Plaintiff, who have used Fosamax for treatment of osteoporosis, have several alternative safer products available to treat this condition.

8. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

9. As a direct result, Plaintiff was prescribed and ingested Fosamax and has been permanently and severely injured. Plaintiff requires and will require ongoing medical care and treatment.

10. Consequently, Plaintiff seeks actual and punitive damages for her injuries resulting from her ingestion of Fosamax, which has caused and will continue to cause Plaintiff to suffer pain, mental anguish and other injuries, as well as to incur significant expenses.

JURISDICTION AND VENUE

11. This Court has jurisdiction pursuant to 28 United States Code §1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a citizen of the State of Oklahoma, and Defendant is incorporated and has its principal place of business in the State of New Jersey. The amount in controversy exceeds seventy thousand dollars ($75,000.00), exclusive of interest and costs.

12. Venue in this action properly lies in the Southern District of New York pursuant to 28 United States Code § 1407 and an order of the Judicial Panel on Multidistrict Litigation dated August 16, 2006 ordering that all actions alleging injury by the ingestion of Fosamax be filed and venued in this district and assigned to the Honorable John F. Keenan.

PARTIES

13. Plaintiff Birdella Blakely is a resident of Boley, Oklahoma.

14. Defendant, Merck & Co., is a New Jersey corporation, which has its principal place of business in Whitehouse Station, New Jersey.

15. At all times material hereto, the Defendant, Merck & Co., was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Fosamax.

16. Defendant is, and was at all relevant times, duly authorized to conduct business in the State of Oklahoma.

17. Defendant, either directly or through its agents, servants, and employees, regularly solicits and transacts business within the State of Oklahoma.

18. Defendant, at all relevant times, has sold and distributed Fosamax in the State of Oklahoma for use in the treatment of osteoporosis or the prevention of osteoporosis.

19. Defendant derives substantial revenue from goods used or consumed in the State of Oklahoma.

20. Defendant expected, or should have expected, that its actions could or would have consequences within the State of Oklahoma.

SUBSTANTIVE ALLEGATIONS

21. In September 1995, Fosamax was approved for marketing and sale in the treatment of osteoporosis and Paget's disease.

22. Fosamax falls within a class of drugs known as bisphosphonates, which are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

23. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphophonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen

atom, whereas etridonate, clodronate, and tiludronate do not. The Physician's Desk Reference ("PDR") listing for Fosamax confirms that the molecule contains a nitrogen atom.

24. Recent studies report the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy

25. Shortly after Defendant began selling Fosamax, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that Fosamax shared the class effects of the other nitrogenous bisphosphonates.

26. Merck knew or should have known that bisphosphonates, including Fosamax, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosponates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

27. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can develop into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

28. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have know that Fosamax, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other nitrogenous bisphosphonates.

29. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to Fosamax. Rather than evaluating and verifying the safety of

Fosamax with respect to osteonecrosis of the jaw, Defendant proposed further uses of Fosamax, such as Fosamax -D, and sought to extend the exclusivity period of Fosamax through 2018.

30. While Fosamax, which remains in the body for years after ingestion, might help bone density in some people, experts now say its benefits for preventing bone fracture are minimal. Additionally, if taken over long periods of time, the drug can make bones more brittle and increase the risk of fracture.

31. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient taking Fosamax.

32. Rather than warn patients and the medical community, and despite knowledge by Defendant of increased risk of osteonecrosis of the jaw on patients using Fosamax, Defendant continued and continues to defend and aggressively market Fosamax, while downplaying any unfavorable findings and overstating its benefits.

33. Fosamax is now the world's top-selling bisphosphonate and Defendant's second-best selling drug, with more than 22 million prescriptions in 2005 amounting to $3.2 billion in sales.

Plaintiff's Use of Fosamax

34. Plaintiff Birdella Blakely was prescribed and took Fosamax from in or about March 2, 2005 through on or about July 1, 2006.

35. Plaintiff used Fosamax as prescribed and for the purpose and in the manner for which it was normally intended.

36. Plaintiff could not by the exercise of reasonable care discover the defective nature and perceive the danger of Fosamax.

37. As a direct and proximate result of using Fosamax, Plaintiff was diagnosed with osteonecrosis of the jaw on or about June 2006.

38. Plaintiff, as a direct and proximate result of using Fosamax, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

39. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug.

COUNT I
Negligence

40. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

41. Defendant had a duty to consumers, including Plaintiff, to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Fosamax.

42. Defendant failed to exercise due care under the circumstances, and therefore breached its duty to Plaintiff.

43. Defendant's negligent acts and omissions, either directly or through its agents, servants, and employees, include, but are not limited to the following:

a. Designing, manufacturing, marketing, advertising, distributing, and selling Fosamax to consumers, including Plaintiff, without an adequate warning of the dangerous risks of Fosamax and without proper instructions to avoid harm caused by Fosamax;

b. Failing to exercise due care when advertising and promoting Fosamax; and

c. Failing to exercise ordinary care by conducting appropriate post-market testing and surveillance of Fosamax.

44. Although Defendant knew, or should have known, of Fosamax's adverse effects Defendant has continued to negligently manufacture, market, advertise, distribute, and sell Fosamax to consumers, including Plaintiff, so as to maximize sale and profits at the expense of public health and safety in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.

45. Defendant knew, or should have known, that consumers, including Plaintiff would suffer injuries as a result of Defendant's failure to exercise ordinary care.

46. As a direct and proximate result of the Defendant's negligence and other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
Strict Liability – Failure to Warn

47. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

48. Defendant designed, tested, manufactured, marketed, sold and/or distributed Fosamax. As such, it had a duty to warn the using public, including Plaintiff, of the health risks associated with using the subject product.

49. The subject product was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding the health risks associated with its use,

including osteonecrosis of the jaw. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injury to the consumer. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

50. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw. Even though Defendant knew or should have known of the risks and reactions associated with the subject product, it still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks.

51. Plaintiff used the subject product for its intended purpose, i.e. for the prevention or treatment of osteoporosis.

52. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

53. Plaintiff would not have used Fosamax had Defendant properly disclosed the risks associated with the drug.

54. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of the subject product.

55. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her.

56. Defendant had a continuing duty to warn consumers, including Plaintiff, of the dangers associated with the subject product. By negligently and/or wantonly failing to adequately warn of the dangers of use of the subject product, Defendant breached its duty.

57. Although Defendant knew of the defective nature of the subject product, they continued to design, manufacture, market, and sell it without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by the subject product.

58. As a direct and proximate result of the Defendant's failure to adequately warn or other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
Strict Liability – Defective Design

59. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

60. Defendant is the manufacturer, seller, distributor, marketer, and/or supplier of the subject product, which is defective and unreasonably dangerous to consumers.

61. The subject product was designed, manufactured, sold, distributed, supplied, marketed, and/or promoted by Defendant, and was expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

62. The subject product was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation.

63. Consumers, including Plaintiff, who have used Fosamax for the prevention or treatment of osteoporosis, have several alternative safer products available to treat this condition.

64. Although Defendant actually knew of the defective nature of the subject product, it continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by the subject product.

65. As a direct and proximate result of the design defects of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
Breach of Express Warranty

66. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

67. Defendant expressly represented to Plaintiff Birdella Blakely, other consumers and the medical community that Fosamax was safe and fit for its intended purposes, of merchantable quality, did not produce any dangerous side effects, and was adequately tested.

68. Fosamax does not conform to Defendant's express representations because it is defective and unfit for its intended purpose, i.e. it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

69. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw.

70. At all relevant times Fosamax did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

71. Plaintiff Birdella Blakely, other consumers and the medical community relied upon Defendant's express warranties.

72. As a direct and proximate result of Defendant's express warranties of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
Breach of Implied Warranty

73. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

74. Defendant designed, tested, manufactured, marketed, sold and/or distributed Fosamax.

75. At all relevant times, Defendant knew of the use for which Fosamax was intended and impliedly warranted the product to be safe and fit for such use.

76. Defendant was aware that consumers, including Plaintiff, would use Fosamax for the prevention or treatment of osteoporosis, and knew, or recklessly disregarded, that consumers,

including Plaintiff, and the medical community relied upon its judgment and sensibility to only sell Fosamax if it was safe and fit for its intended use.

77. Defendant herein breached its implied warranty to consumers, including Plaintiff; Fosamax was not safe or fit for its intended use.

78. Consumers, including Plaintiff, and the medical community reasonably relied upon Defendant's implied warranty for Fosamax.

79. Fosamax reached Plaintiff without substantial change in the condition in which it was manufactured and sold by Defendant.

80. As a direct and proximate result of Defendant's implied warranties of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
Common Law Fraud

81. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

82. Defendant falsely and fraudulently represented to the medical community, and to the Plaintiff and the public in general, that Fosamax had been tested and found to be safe and effective for the prevention and treatment of osteoporosis.

83. Defendant knew, or should have known, that its representations were false yet it willfully, wantonly and recklessly disregarded its obligation to provide truthful representations

regarding the safety and risks of Fosamax to consumers, including Plaintiff, and the medical community.

84. Defendant's representations were made with the intent of defrauding and deceiving consumers, including Plaintiff, and the medical community, with the intent of encouraging and inducing sales of Fosamax.

85. Defendant knowingly, consciously, and deliberately placed its financial gain above the rights and safety of Plaintiff and other consumers.

86. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

87. Plaintiff was unaware of the falsity of Defendant's representations and reasonably relied upon Defendant's representations, thereby developing osteonecrosis of the jaw.

88. As a direct and proximate result of Defendant's fraudulent misrepresentation of the subject product, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
Punitive Damages

89. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

90. Although Defendant knew or recklessly disregarded the fact that the subject product causes debilitating and potentially lethal side effects, Defendant continued to market the subject product to consumers, including Plaintiff, without disclosing these side effects.

91. Defendant knew of the subject product's defective nature, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the subject product.

92. Defendant intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of the subject product to ensure their continued and increased sales. This intentional and/or reckless failure to disclose information deprived Plaintiff of the information necessary for her to weigh the true risks of using the subject product against the benefits.

93. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendant and it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
Violation of Oklahoma Consumer Protection Act, 15 Okl.St.Ann. § 753

94. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

95. Defendant's misrepresentations and concealment of material fact constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression or omission of material facts with the intent that

others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Fosamax.

96. Defendant engaged in the deceptive acts and practices alleged herein in order to sell a consumer product, Fosamax, to the public, including Plaintiff.

97. Defendant intentionally concealed facts known to it, as alleged herein, in order to ensure the increased sales of Fosamax.

98. Defendant's conduct, as alleged herein, was likely to mislead a reasonable consumer, such as Plaintiff, acting reasonably under the circumstances to believe that Fosamax was a safe treatment for osteoporosis.

99. As a direct and proximate result of Defendant's actions, Plaintiff has sustained serious and permanent injuries, and will continue to suffer, injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays of this Court and demands of Defendant as follows:

a. That Plaintiff be granted and recover actual damages incidental to her purchase and use of Fosamax in an amount to be determined at trial;

b. That Plaintiff be granted and recover treble and punitive damages;

c. That Plaintiff be granted pre-judgment and post-judgment interest;

d. That the costs of this action be taxed to Defendant;

e. That Plaintiff be granted reasonable attorneys' fees and costs as provided by law; and

f. For such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

The Plaintiff demands a trial by jury on all issues.

Dated: May 1 , 2008

SEEGER WEISS LLP

By: _____

Christopher A. Seeger (CS-4880)
David R. Buchanan (DB-6368)
Jeffrey S. Grand
SEEGER WEISS LLP
One William Street
New York, NY 10004
(212) 584-0700 tel.
(212) 584-0799 fax.

Attorneys for Plaintiff